EXTRANEAL Peritoneal Dialysis Solution with 7.5% Icodextrin
License No. 023687

Prescription drug only
For intraperitoneal administration only

Product name
EXTRANEAL Peritoneal Dialysis Solution with 7.5% Icodextrin

Composition
EXTRANEAL is a sterile solution for intraperitoneal administration.
Each 100 ml of EXTRANEAL contains: Electrolyte solution content per 1000 ml:
Icodextrin 7.5 g Sodium 132 mmol
Sodium Chloride 538 mg Calcium 1.75 mmol
Sodium Lactate 448 mg Magnesium 0.25 mmol
Calcium Chloride 25.7 mg Chloride 96 mmol
Magnesium Chloride 5.06 g Lactate 40 mmol
Theoretical osmolality 284 (milliosmoles per litre).

Excipient
EXTRANEAL also contains: Water for injections.

Pharmaceutical form and Pharmaceutical Properties
EXTRANEAL is a sterile peritoneal dialysis fluid containing Icodextrin as the active ingredient at a concentration of 7.5%, in an electrolyte solution. It should not be used for intravenous administration. EXTRANEAL is presented in flexible PVC containers and is available in the following bag sizes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Fill Volume (mL)</th>
<th>Container Size (mL)</th>
<th>Product Configuration</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>FNB4974</td>
<td>2000</td>
<td>2000</td>
<td>AMBU-FLEX</td>
<td>6</td>
</tr>
<tr>
<td>FNB4982</td>
<td>1500</td>
<td>2000</td>
<td>ULTRABAG</td>
<td>8</td>
</tr>
<tr>
<td>FNB4984</td>
<td>2000</td>
<td>2000</td>
<td>ULTRABAG</td>
<td>6</td>
</tr>
</tbody>
</table>

Properties
Icodextrin is a starch-derived glucose polymer which acts as an osmotic agent when administered intraperitoneally for continuous ambulatory peritoneal dialysis (CAPD). EXTRANEAL produces sustained ultrafiltration over a period up to 12 hours in CAPD, with a reduction in caloric load compared to 4.25% Dextrose solutions, but with similar volume of ultrafiltrate.

Therapeutic Indications
EXTRANEAL is recommended for the treatment of chronic renal failure.

Contraindications
EXTRANEAL is contraindicated in patients with:
- a known allergy to starch-based polymers (e.g. corn starch) and/or Icodextrin
- malaise or isomaltose intolerance
- glycogen storage disease
- pre-existing severe lactic acidosis
- uncorrectable mechanical defects that prevent effective PD or increase the risk of infection
- documented loss of peritoneal function or extensive adhesions that compromise peritoneal function

Precautions for Use
EXTRANEAL is intended for intraperitoneal administration only. Not for intravenous administration.

- To change the dialysis bag, it is of vital importance that all the steps shown during training are carefully followed and to ensure that all the connecting parts remain completely clean to reduce the possibility of infection.
- Do not administer if the solution is discolored, cloudy, contains particulate matter or shows evidence of leakage or if seals are not intact.
- The drained fluid should be inspected for the presence of fibrin or cloudiness, which may indicate the presence of peritonitis.
- Safety and effectiveness in pediatric patients have not been established.
- Protein, amino acids, water-soluble vitamins, and other medicines may be lost during peritoneal dialysis and may require replacement.

- Peritoneal dialysis should be done with caution in patients with:
  1. abdominal conditions, including disruption of the peritoneal membrane and diaphragm by surgery, from congenital anomalies or trauma until healing is complete, abdominal tumors, abdominal wall infection, hernias, fecal fistula, colostomy, or ileostomy, frequent episodes of diverticulitis, inflammatory or ischemic bowel disease, large polycystic kidneys, or other conditions that compromise the integrity of the abdominal wall, abdominal surface, or intra-abdominal cavity: and
  2. other conditions including aortic graft placement and severe pulmonary disease.
- An accurate fluid balance record should be kept and the patient's body weight monitored. Patients should be carefully monitored to avoid over- and underhydration.
- Overinfusion of an EXTRANEAL volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath.
- Treatment of EXTRANEAL overinfusion is to drain the EXTRANEAL from the peritoneal cavity.
- Potassium is omitted from EXTRANEAL solutions due to the risk of hyperkalemia.
- In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia and should be made after careful evaluation of serum and total body potassium, only under the direction of a physician.
- Fluid, hematocrit, blood chemistry, and electrolyte concentrations should be monitored periodically, including, magnesium and bicarbonate. If serum magnesium levels are low, oral magnesium supplements or peritoneal dialysis solutions containing higher magnesium concentrations may be used.
- In diabetic patients, blood glucose levels should be regularly monitored, and the dosage of insulin or other treatment for hyperglycemia should be adjusted following initiation of treatment with EXTRANEAL.
- Decreases in serum sodium and chloride have been observed in patients using EXTRANEAL.

Special Warnings
Blood glucose measurement must be done with a glucose-specific method to prevent malaise interference.

Glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO) – based methods must not be used. Also, the use of some glucose monitors and test strips using glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) methodology has resulted in falsely elevated glucose readings due to the presence of maltose. The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose results.

If GDH-PQQ, GDO, or GDH-FAD-based methods are used, using EXTRANEAL may cause a falsely high glucose reading, which could result in the administration of more insulin than needed. Administration of more insulin than needed has caused hypoglycemia, which has resulted in loss of consciousness, coma, neurological damage, and death.

Additionally, falsely elevated blood glucose measurements due to malaise interference may mask true hypoglycemia and allow it to go untreated with similar consequences.

Falsely elevated glucose levels may be measured up to two weeks following cessation of EXTRANEAL (icodextrin) therapy when GDH-PQQ, GDO, or GDH-FAD-based blood glucose monitors and test strips are used.

Because GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors may be used in hospital settings, it is important that the health care providers of all peritoneal dialysis patients using EXTRANEAL (icodextrin) carefully review the product information of the blood glucose testing system, including that of test strips, to determine if the system is appropriate for use with EXTRANEAL (icodextrin).

To avoid improper insulin administration, educate all patients on EXTRANEAL therapy to alert health care providers of this interaction whenever they are admitted to the hospital.

- Encapsulating peritoneal sclerosis (EPS) is considered to be a known, rare complication of peritoneal dialysis therapy. EPS has been reported in patients using peritoneal dialysis solutions including EXTRANEAL. Infrequently, fatal outcomes of EPS have been reported with EXTRANEAL.
- If peritonitis occurs, the choice and dosage of antibiotics should be based upon the results of identification and sensitivity studies of the isolated organism(s) when possible. Prior to identification of the involved organism(s), broad-spectrum antibiotics may be necessary.
- Rarely, serious hypersensitivity reactions to EXTRANEAL have been reported such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme and vasculitis. Anaphylactic/anaphylactoid reactions may occur. Stop the infusion immediately and drain the solution from the peritoneal cavity if any signs or symptoms of a suspected
hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.
- Patients with severe lactic acidosis should not be treated with lactate-based parenteral dialysis solutions. (See Contraindications) It is recommended that patients with conditions known to increase the risk of lactic acidosis (e.g., severe hypotension or sepsis that can be associated with acute renal failure; iornborn of metabolites; treatment with drugs such as metformin and nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs)) must be monitored for occurrence of lactic acidosis before the start of treatment and during treatment with lactate-based parenteral dialysis solutions.
- When prescribing the solution to be used for an individual patient, consideration should be given to the potential interaction between the dialysis treatment and therapy directed at other existing illnesses. Serum potassium levels should be monitored carefully in patients treated with cardiac glycosides.

Pregnancy and Lactation
There are no adequate data from the use of EXTRANEL in pregnant or lactating women. EXTRANEL is not recommended during pregnancy or while breast feeding. Women of childbearing potential should be treated with EXTRANEL only when adequate contraceptive precautions have been taken. Potential effects on male and female fertility are unknown.

Interactions with other Medicaments and other forms of Interaction
No interaction studies have been conducted with EXTRANEL. The blood concentration of dialyzable drugs may be reduced by parenteral dialysis.

Drug-Laboratory Test Interferences
- Blood glucose measurement must be done with a glucose-specific method to prevent malse test interference. Glucose dehydrogenase pyridoxalinequinone (GDH-PQD), glucose-3-endoxidoreductase (GLO3)– based methods must not be used. Also, the use of some glucose monitors and test strips using glucose dehydrogenase flavin-adinit dehydrogenase (GDH-FAD) methodology has resulted in falsely elevated glucose readings due to the presence of malse. See Special Warnings and Precautions for use.
- An apparent decrease in serum amylose activity has been observed in patients administered EXTRANEL.

Patients using cardiac glycosides should carefully monitor blood electrolytes level, such as calcium, potassium, magnesium.

Effects on Ability to Drive and Use Machines
End stage renal disease (ESRD) patients undergoing peritoneal dialysis may experience undesirable effects, which could affect the ability to drive or use machines.

Incompatibilities
- Consult with pharmacist familiar with peritoneal dialysis, if available. If, in the informed judgment of the physician, it is deemed advisable to add additives, use aseptic technique.
- Refer to directions for use accompanying drugs to obtain full information on additives.
- Some drug additives may be incompatible with EXTRANEL.
  > Addition of Potassium
  Potassium is omitted from EXTRANEL solutions because dialysis may be performed to correct hypokalemia. In situations where there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. The decision to add potassium chloride should be made by the physician after careful evaluation of serum potassium.
  > Addition of Insulin
  Addition of insulin to EXTRANEL was evaluated in 6 insulin-dependent diabetic patients undergoing CAPD for end stage renal disease. No interference of EXTRANEL with insulin absorption from the peritoneal cavity or with insulin’s ability to control blood glucose was observed. (See Interactions With Other Medicinal Products and Other Forms of Interaction). Appropriate monitoring of blood glucose should be performed when initiating EXTRANEL in diabetic patients and insulin dosage adjusted if needed. (See Special Warnings and Precautions for Use).
  > Addition of Heparin
  No human drug interaction studies with heparin were conducted. In vitro studies demonstrated no evidence of incompatibility of heparin with EXTRANEL.
  > Addition of Antibiotics
  No formal clinical drug interaction studies have been performed. In vitro compatibility studies with EXTRANEL and the following antibiotics have demonstrated no effects with regard to minimum inhibitory concentration (MIC): vancomycin, cephalothin, ampicillin/sulfoxacillin, cefazolin, gentamicin, and amphotericin. However, aminglycosides should not be mixed with penicillin due to chemical incompatibility.

Dosage and Method of Administration

Dosage
The volume to be instilled should be given over a period of approximately 10 to 20 minutes at a rate which patients find comfortable. For adult patients of normal body size the inlaid volume should not exceed 2.0 litres. If this causes abdominal tension a 1.5 litre volume should be used. The recommended dwell time is between 6 and 12 hours in CAPD and 14-16 hours in APD.

Adverse Reactions
The adverse reactions within this section represent those that are thought to have an association with use of EXTRANEL or in conjunction with performing the peritoneal dialysis procedure.

Adverse Reactions from Clinical Trials

<table>
<thead>
<tr>
<th>System Organ Class (SOC)</th>
<th>Clinical Trial Adverse Reactions</th>
<th>Frequency*</th>
<th>Frequency Percentage or Ratio N=493</th>
</tr>
</thead>
<tbody>
<tr>
<td>INFECTIONS AND INFESTATIONS</td>
<td>Influenza, Furuncle Infection</td>
<td>Uncommon</td>
<td>Uncommon, Uncommon, Uncommon</td>
</tr>
<tr>
<td>BLOOD AND LYMPHATIC SYSTEM DISORDERS</td>
<td>Anemia, Leukocytosis, Esinophil</td>
<td>Uncommon</td>
<td>Uncommon, Uncommon, 0.2</td>
</tr>
<tr>
<td>ENDOCRINE DISORDERS</td>
<td>Parathyroid disorder</td>
<td>Common</td>
<td>Common, Common, Common</td>
</tr>
<tr>
<td>METABOLISM AND NUTRITION DISORDERS</td>
<td>Dehydration, Hypovolemia, Hypoglycemia, Hypoproteinemia</td>
<td>Common</td>
<td>Common, Common, Common, Common</td>
</tr>
<tr>
<td>PSYCHIATRIC DISORDERS</td>
<td>Thinking abnormal, Anxiety, Nervousness</td>
<td>Uncommon</td>
<td>Uncommon, Uncommon, Uncommon</td>
</tr>
<tr>
<td>NERVOUS SYSTEM DISORDERS</td>
<td>Dizziness, Headache, Hypertension, Paraphrenia, Agnesia</td>
<td>Common</td>
<td>Common, Common, Common, Common, Common</td>
</tr>
<tr>
<td>EAR AND Labyrinth DISORDERS</td>
<td>Tinnitus</td>
<td>Common</td>
<td>Common</td>
</tr>
<tr>
<td>CARDIAC DISORDERS</td>
<td>Cardiac disorder, Tachycardia</td>
<td>Uncommon</td>
<td>Uncommon, Uncommon</td>
</tr>
<tr>
<td>VASCULAR DISORDERS</td>
<td>Hypotension, Hypertension, Orthostatic hypotension</td>
<td>Common</td>
<td>Common, Common, Common</td>
</tr>
<tr>
<td>RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS</td>
<td>Pulmonary edema, Dypnea, Cough, Acute respiratory distress syndrome, Lung disorder</td>
<td>Uncommon</td>
<td>Uncommon, Uncommon, Uncommon, Uncommon</td>
</tr>
</tbody>
</table>

*Common, Uncommon, Rare
### Clinical Trial Adverse Reactions

<table>
<thead>
<tr>
<th>System Organ Class (SOC)</th>
<th>Preferred MedDRA Term</th>
<th>Frequency*</th>
<th>Frequency Percentage or Ratio N=483</th>
</tr>
</thead>
<tbody>
<tr>
<td>GASTROINTESTINAL DISORDERS</td>
<td>Abdominal pain</td>
<td>Common</td>
<td>1.6</td>
</tr>
<tr>
<td></td>
<td>Abdominal distension</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Intestinal obstruction</td>
<td>Uncommon</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>Peritonitis</td>
<td>Uncommon</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>Bloody peritoneal effluent</td>
<td>Uncommon</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>Diarrhea</td>
<td>Uncommon</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>Gastric ulcer</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Gastritis</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Gastrointestinal disorder</td>
<td>Uncommon</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>Vomiting</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Constipation</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Dyspepsia</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Nausea</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Dry Mouth</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Flatulence</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td>SKIN AND SUBCUTANEOUS DISORDERS</td>
<td>Dermatitis exfoliative</td>
<td>Common</td>
<td>1.6</td>
</tr>
<tr>
<td></td>
<td>Rash</td>
<td>Common</td>
<td>5.5</td>
</tr>
<tr>
<td></td>
<td>Pruritus</td>
<td>Uncommon</td>
<td>1.4</td>
</tr>
<tr>
<td></td>
<td>Urticaria</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Dermatitis bullous</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Psoriasis</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Rash, macular-papular</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Skin ulcer</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Eczema</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Nail disorder</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Skin disorder</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Dry skin</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Skin discolouration</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td>MUSCULOSKELETAL, CONNECTIVE TISSUE DISORDERS</td>
<td>Bony pain</td>
<td>Uncommon</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>Muscle spasm</td>
<td>Uncommon</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>Myalgia</td>
<td>Uncommon</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>Neck pain</td>
<td>Uncommon</td>
<td>0.4</td>
</tr>
<tr>
<td>RENAL AND URINARY DISORDERS</td>
<td>Renal pain</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td>GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS</td>
<td>Edema peripheral</td>
<td>Common</td>
<td>1.4</td>
</tr>
<tr>
<td></td>
<td>Anorexia</td>
<td>Uncommon</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>Chest pain</td>
<td>Uncommon</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>Catheter-related complication</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Face edema</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Edema</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Pain</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td>INVESTIGATIONS</td>
<td>Urine output decreased</td>
<td>Common</td>
<td>2.6</td>
</tr>
<tr>
<td></td>
<td>Laboratory test abnormal</td>
<td>Uncommon</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>Aspartateaminotransferase increased</td>
<td>Uncommon</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>Blood alkaline phosphatase increased</td>
<td>Uncommon</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>Liver function test abnormal</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Weight decreased</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Weight increased</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
<tr>
<td>INJURY, POISONING, AND PROCEDURAL COMPLICATIONS</td>
<td>Injury</td>
<td>Uncommon</td>
<td>0.2</td>
</tr>
</tbody>
</table>

* Frequency has been evaluated using the following criteria: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (<1/10,000 to ≤1/1000), very rare (<1/10,000). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

** This table represents an integration of safety data from the following clinical trials of 493 patients: RD-07-CA-165, RD-07-CA-131, M/L18031, PPD-Reg-05/05, M/L18232 (CEI), M/L18231 (DANA), M/L1824 (Waks-2), RD-06-CA-092, and M/L18234 (Waks-2). The table also includes adverse events from 10 clinical studies B/L-82-G21. Additionally, safety data from studies B/L-82-G22, RD-06-CA-050 and RD-06-CA-032 were reviewed and did not require additions to the clinical trial data presented.

** Reported in 1 of 18 patients who were exposed to EXTRANEL in clinical trial B/L-82-G21. Therefore, estimation of frequency not presented due to limited patient population in clinical trial B/L-82-G21.

### Post-Marketing Adverse Reactions

In addition to the adverse reactions noted in clinical trials, the following adverse reactions have been reported in the post-marketing experience. These reactions are listed by MedDRA System Organ Class (SOC), then by Preferred Term in order of severity.

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### Special Precautions for Storage

EXTRANEL has a shelf life of 2 years. Do not use the product after expiry date shown on the carton and product label. Store at temperature below 30°C. Do not use unless the solution is clear and the container undamaged. Keep out of reach of children. Any unused portion of dialysis solution in a bag should be discarded.

Name and address of manufacturer

Baxter Healthcare SA, Singapore Branch
2 Woodlands Industrial Park D Street 2, Singapore 737778

Date of revision

PPD-25-369 Mar 2020

EXTRANEL, AMBU-FLEX AND ULTRABAG are trademarks of Baxter International Inc.
“百特”愛多尼爾腹膜透析液

EXTRANEA Peritoneal Dialysis Solution with 7.5% Icodextrin

表

<table>
<thead>
<tr>
<th>產品名稱</th>
<th>包裝容量 (mL)</th>
<th>包裝單位</th>
</tr>
</thead>
<tbody>
<tr>
<td>FN9874</td>
<td>2000</td>
<td>AMBU-FLEX 6</td>
</tr>
<tr>
<td>FN9892</td>
<td>1500</td>
<td>雙袋裝 8</td>
</tr>
<tr>
<td>FN9894</td>
<td>2000</td>
<td>雙袋裝 8</td>
</tr>
</tbody>
</table>

**特性和安全性**

Icodextrin是高聚糖類的多聚合物，主要作用是在透析活動中透析液（CAPD）中產生的生理機制。EXTRANEA在透析30小時之腸道可自動用於透析活動，仍可保持良好的透析效果。相對於通過酸敗雜質之4.25%葡萄糖透析液，EXTRANEA可減輕這些在透析活動中急劇增高的熱視線。

**使用注意事項**

- **零售商**
  - **繪製**
  - **製造**
  - **包裝**
  - **使用**
  - **棄置**

**使用注意事項**

EXTRANEA僅供醫療用途，不可用於飲用。

- **更換飲料法**
  - **內容物**
  - **製造**
  - **包裝**
  - **使用**

**注意事項**

- **飲用**
  - **製造**
  - **包裝**
  - **使用**

**警告及警告標記**

- **醫療**
  - **製造**
  - **包裝**
  - **使用**

**使用注意事項**

- **飲用**
  - **製造**
  - **包裝**
  - **使用**
### 不相容性
- 若有可能，請諮詢熟悉應用藥物的藥劑師，並請無菌技術
- 請參考藥物相互作用指南，以取得有關添加其他藥物的詳細資訊。
- 某些藥物添加可能與藥物 EXTRANEA 不相容。
- **加藥**
  - EXTRANEA 液體中不添加抗氧劑因為抗氧劑可能是用來預防治療的。
  - 在正常的情況下，磷酸氫鈣及磷酸氫鈣的分解在一般情況下，可能有必需要添加抗氧剎（濃度為 4％到 8％）。
  - 以正常速度抗氧剎，但需在無抗氧剎和磷酸氫鈣進行比較評估後，再行藥物指導
- **添加抗氧剎**
  - 在添加抗氧剎時，其方式是含有抗氧剎的高含量抗氧剎溶液，以其他藥物的交互作用
  - 及其與其他藥物的交互作用進行比較評估後，再行藥物指導
- **添加藥物**
  - 藥物的人體藥物相互作用研究尚未開板，未臨床研究中發現 EXTRANEA 與藥
  - 物無相互作用的問題。
- **添加抗血清**
  - 正式的臨床藥物相容性研究尚未進行，EXTRANEA 與下列抗生素的
  - 相容性研究已顯示，對下列抗生素藥物相容性測試，未發現影響
  - vancomycin、cefazolin、penicillin G、cefuroxime、amoxicillin、ampicillin
  - 及 amphotericin B，這是因為藥物相容性不能與對病人有基於生理因素，因病人而異的

### 用藥及用法
**用量：**
- 藥剎在 10 到 30 分鐘的使用時間，在病房內切穿膿胸，次性添加，中等體重
  - 的病患，每 20 分鐘可補充 1.5 公升，每 4 小時可補充 5.0 公升，按
  - 病況活動時活性藥剎，1 次每 15 分鐘，至 12 小時，及全身自動腹膜透析
  - (APD) 病人建議留置時間為 14-16 小時。

**用途：**
- **EXTRANEA** 專用於腹膜透析，不可靜脈注射。
- 需在病人治療的適當時間注入 EXTRANEA，使用溶劑由處方醫師決定。
- 治療方式、治療頻率、接觸時間、使用時間的時間，應由處方醫師和
  - 病人協議決定。
- **貯存與溫度**
  - 在冷凍使用的不乾冰，可將透析液溫度升高的體溫 37℃（98.6°F），為避免透析器的
  - 使用或不使用，如需採用乾燥方式，如電熱紙、保溫袋，不可在水中或在微
  - 波爐中加熱。

**製造過程**
- 未使用任何藥物，至少使用乾燥藥物，並確保符合國家標準。
- **紫外線**
  - 被紫外線照射，可能對藥物或透明瓶損壞或破裂，最終影響治療。
- **棄置**
  - 押紗材料的剩餘溶液，因未使用，不可回覆使用。
- **一次性使用**

### 特殊注意：
- **成人**
  - 作為腹膜透析療法的一部分，本產品每日僅使用一次，並用於短療程。
- **兒童**
  - 同成年。
- **兒童**
  - 不建議兒童使用 EXTRANEA。

### 不良反應
- 本部分的不良反應，是使用與 EXTRANEA 相關的藥物，藥物或粉末崩解過程相關的
  - 不良反應。

### 臨床試驗中的不良反應

<table>
<thead>
<tr>
<th>分類 (SOC)</th>
<th>MedDRA 適用詞</th>
<th>出現頻率</th>
<th>頻率百分比或 比例 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>感染</td>
<td>一般感染</td>
<td>不常見</td>
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<tr>
<td>感染</td>
<td>疫苗反應</td>
<td>不常見</td>
<td>0.2</td>
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<tr>
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<td>感染</td>
<td>不常見</td>
<td>0.2</td>
</tr>
<tr>
<td>血液和血液系統疾病</td>
<td>發熱</td>
<td>不常見</td>
<td>0.4</td>
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<td>血液和血液系統疾病</td>
<td>白血球增多</td>
<td>不常見</td>
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<tr>
<td>血液和血液系統疾病</td>
<td>增加白細胞等</td>
<td>不常見</td>
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<tr>
<td>內分泌系統</td>
<td>副腎機能障礙</td>
<td>不常見</td>
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<td>不常見</td>
<td>0.2</td>
</tr>
</tbody>
</table>

### 症狀
- **發熱**
  - 不常見   | **2.0**        |
- **高血壓**
  - 常見     | **1.0**        |
- **高血壓**
  - 常見     | **0.2**        |
- **高血壓**
  - 不常見   | **0.4**        |
- **高血壓**
  - 不常見   | **0.2**        |
- **高血壓**
  - 不常見   | **0.4**        |
- **高血壓**
  - 不常見   | **0.2**        |
- **高血壓**
  - 不常見   | **0.4**        |
- **高血壓**
  - 不常見   | **0.2**        |

**注**：
- 常見度是指不必要的症狀，症狀是 (1/100)，症狀 (1/1000) 到 (1/10000)，症狀 (1/100000)到 (1/1000000)，症狀 (1/10000000)。
蘋果醫療產品股份有限公司

最近一次修改仿單的時間

2020年3月

EXTRANALE、AMBO-FLEX 及 ULTRABAG 是百特國際有限公司的產品商標。